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Dockets Management Branch (HFA-305)
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Re: Comments on, "Guidance for Industry: Part 11, Electronic Records; Electronic Signatures -- Scope and Application", Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539

Dear Sir or Madam:

SEC Associates, Inc. (SEC) is pleased to have the opportunity to provide comments on the above-referenced draft guidance.

We see positive benefits resulting from this guidance and the planned re-examination of Part 11. Chief among these benefits are the ability to apply a science- and risk-based approach to compliance, as well as the clarification of confusing issues and "folklore" that have evolved since Part 11 was enacted. However, we also see the potential for further confusion and misinterpretations due to questions left unanswered by the draft guidance. We believe certain issues merit further clarification in order to maximize the benefits of this "re-direction", while at the same time assuring that safety, efficacy, and quality are not compromised in the process.

Our comments and suggestions are attached. Thank you again for the opportunity to express our views.

Very truly yours,
SEC ASSOCIATES, INC.

John C McKenney Sr

John C. McKenney, Sr.
President

attachment

00D-1542 C26